

ALLEGED SHIPMENT: On or about February 8, 1947, by R. J. Prentiss & Co., Inc., from New York, N. Y.

PRODUCT: 300 bags, containing a total of 10,078 pounds, of *cascara sagrada* at Freeport, Ill.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the official standard, since the Pharmacopoeia provides that vegetable drugs are to be as free as practicable from molds and shall show no abnormal discoloration, whereas the article was contaminated with mold and was discolored.

DISPOSITION: August 5, 1947. W. T. Rawleigh Co., Freeport, Ill., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for segregation and destruction of the unfit portion, under the supervision of the Federal Security Agency. The segregation operations resulted in the destruction of 25 bags of the product as unfit.

2319. Adulteration and misbranding of antiseptic mouth wash and misbranding of witch hazel. U. S. v. James J. Kaplan (Diamond Drug and Magnesia Co.). Plea of guilty. Fine, \$100. (F. D. C. No. 21472. Sample Nos. 12714-H, 12734-H, 56689-H, 56845-H.)

INFORMATION FILED: August 22, 1947, District of Massachusetts, against James J. Kaplan, trading as the Diamond Drug & Magnesia Co., at Boston, Mass.

ALLEGED SHIPMENT: On or about October 18, 1945, and January 7 and February 2 and 7, 1946, from the State of Massachusetts into the States of New Hampshire, Rhode Island, and Maine.

LABEL, IN PART: "Berkeley Brand Antiseptic Mouth Wash * * * Distributed by Berkeley Drug & Chemical Co., Boston, Mass.," "Peerless Antiseptic Mouth Wash * * * Distributed by Peerless Products Co., Boston Mass.," "Eluto's Witch Hazel * * * Distributed by Eluto Bros., Inc., Manchester, N. H.," or "Nyler Quality Products Witch Hazel * * * Eastern Distributor The Jayson Co., Portland, Maine."

NATURE OF CHARGE: *Antiseptic mouth wash.* Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it was represented to possess, in that it was represented to be an antiseptic when diluted to one-half strength, whereas when diluted to one-half strength it was not an antiseptic within the meaning of Section 201 (o), since it was not a germicide when so diluted and did not purport to be and was not represented as an antiseptic for inhibitory use as a wet dressing ointment, dusting powder, or such other use as involved prolonged contact with the body. Misbranding, Section 502 (a), the label statement "Antiseptic * * * Use ½ * * * strength" was false and misleading.

Witch hazel. Misbranding, Section 502 (a), the label statements "For the relief of Sprains, Bruises * * * Burns, Scalds * * * Chilblains" were false and misleading, since they represented and suggested that the article would be an effective treatment for sprains, burns, bruises, scalds, and chilblains, whereas it would not be an effective treatment for such conditions.

DISPOSITION: March 2, 1948. A plea of guilty having been entered, the court imposed a fine of \$100.

2320. Adulteration and misbranding of prophylactics. U. S. v. Crown Rubber Sundries Co. and Joseph Lader. Pleas of not guilty. Tried to the court. Verdict of guilty. Fine, \$800 and costs. (F. D. C. No. 15578. Sample Nos. 105-H, 2589-H, 13537-H, 22909-H.)

INFORMATION FILED: August 23, 1945, Northern District of Ohio, against the Crown Rubber Sundries Co., a partnership, Akron, Ohio, and Joseph Lader, a partner.

ALLEGED SHIPMENT: On or about January 18 and February 15 and 28, 1945, from the State of Ohio into the States of Florida, West Virginia, Indiana, and Missouri.

LABEL, IN PART: (Boxes) "Red-Pak * * * Packed by W. H. Reed & Co. Atlanta, Ga. [or "Packed by Crown Rubber Co. Akron, Ohio"]," "Red-Pack * * * Manufactured by Killian Mfg. Co. Akron, Ohio," or "Seal-Tex * * * Seal Rubber Co. Akron, Ohio"; (portions of devices) "Genuine Liq-

uid Latex Mfd. by L. E. Shunk Latex Prod. Inc., Akron, Ohio," or "Mfd. By Shunk Latex Prod. Inc. Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess. The article purported to be and was represented as a prophylactic, but would be ineffective for prophylactic purposes because of the presence of holes and perforations.

Misbranding, Section 502 (a), the following statements appearing in the labeling of the various shipments were false and misleading: "Prophylactic," "For prevention of disease," "Prophylactics * * * guaranteed for five years," "For prevention of disease only," "The Pink of Perfection * * * Prophylactics * * * Made From the Highest Quality of Pure Rubber * * *," and "Guaranteed to Conform to All Regulations * * * The within articles are manufactured to be sold and used for the prevention of disease."

DISPOSITION: May 27, 1946. Pleas of not guilty having been entered, the matter was tried before the court. The defendants were found guilty and were fined \$2,400, together with costs. On July 12, 1946, the court handed down the following memorandum opinion:

FREED, District Judge: "The matter for decision involves the interpretation of Title 21 U. S. C. A. § 333 (c).

"What is the extent of the immunity granted by this section to a distributor, who has branded and sold a product relying upon a guaranty of compliance with the Federal Food, Drug and Cosmetic Act, received from his manufacturer or seller in good faith?

"The essential facts are not in dispute.

"Crown Rubber Sundries Co., a partnership; and one of the partners, individually, Joseph Lader, were charged in eight counts of an information alleging violation of Title 21 U. S. C. A. 331 (a) and Title 21 U. S. C. A. 352 (a) in the shipment and sale of rubber prophylactics which were, in fact, ineffective for prophylactic purposes because of the presence of holes and perforations in the devices.

"It is not disputed that the goods shipped in interstate commerce were adulterated and misbranded.

"The defendants rely solely upon the claim that they are free from guilt because they received a guaranty given them by the L. E. Shunk Latex Products Inc., the manufacturer, warranting that all the merchandise complied with the provisions of the Pure Food, Drug and Cosmetic Act, and authorizing them to make the same guaranty to their distributees.

"The undisputed facts show that the defendants received the merchandise in bulk, that they repacked the prophylactics in individual containers bearing their own labels and shipped them to their own customers. There was some evidence tending to show that the merchandise was acquired by the purchase of a wholesale business which had in stock the prophylactics which the original owner had purchased from the Shunk Company.

"Since the purchase was not made directly from the manufacturer, it is questioned whether the guaranty made to these defendants could inure to their benefit. It is urged by the Government that the guaranty which affords a defense is only one which is made to him who purchases directly from the guarantor.

"Although the court is of the opinion that the Government's contention in this regard is correct, the real issue is whether the defense of the guaranty, as a matter of law, can be made under the state of the evidence which is not in dispute.

"Assuming, for the purpose of the instant case, that the defendants did have a right to rely upon a guaranty received from someone other than the person from whom they purchased the merchandise, the question remains whether the guaranty affords a defense under the statute.

"The decided cases have not dealt with the question here raised. The report of the Congressional committees throws no light upon the intent of Congress as affects the immediate issue.

"The effect of the guaranty, in the Committees' report, is touched upon briefly as affording protection to a manufacturer who ships his products to distant processors who, in turn, package and label the finished merchandise. The committees' report indicates it was the intent of Congress to relieve the

manufacturer of the effect of violations of the Act that result from the processing of his products by others for whom the manufacturer should not be liable.

"Neither the reported cases, nor the Committees' report deals with the question of the defense available to the shipper who holds a guaranty from the manufacturer.

"It is fundamental that the purpose of the Act is to protect the consumer. Public policy casts upon those who introduce foods, drugs and cosmetics into interstate commerce the duty of rigid inspection. They are charged with absolute responsibility for proper branding of their products. Public safety demands of them not only extreme care, but definite assurance of the quality of their products.

"It is the judgment of this court that no person may rely upon any guaranty unless, in introducing the product into interstate commerce, he has acted merely as a conduit through which the merchandise reaches the consumer.

"The protection of the exemption clause of the statute does not include within its ambit those who, in any way handle or process the product to which the guaranty attaches, if one has been given.

"The guaranty can be received in good faith, within the meaning of the statute, only if the shipper passes the product on in the same form as he receives it, without repacking it or subjecting it to any new hazards of adulteration or failure which were not present when the original guaranty upon which he relies was given.

"The facts in this case show the prophylactics were purchased by the defendants in bulk and that they repackaged and relabeled them. They shipped them in cartons bearing their own trade name.

"When this state of facts appears, in the judgment of the court, as a matter of law, the defense of the guaranty no longer is available to the defendants.

"Such an interpretation, the court believes, would be in accord with the intent of Congress, as reflected both by the general purpose of the Act and the language of the Committees in treating the extent of the defense available to the manufacturer.

"Since the defense of the guaranty is not available to the defendants, and since the evidence establishes every other element of the offenses charged, it is the judgment of the court that they must be found guilty of the violations charged in the information."

On February 11, 1947, the defendants having petitioned for a mitigation of the sentence, the court reduced the fine from \$2,400 to \$800.

2321. Adulteration and misbranding of prophylactics. U. S. v. Allied Latex Corporation. Plea of guilty. Fine, \$5,400. (F. D. C. No. 5579. Sample Nos. 5557-E, 5558-E, 19662-E, 27493-E, 27494-E, 36368-E, 39501-E, 39985-E, 42958-E, 48610-E, 48611-E, 48613-E, 48615-E, 48616-E, 48618-E to 48621-E, incl., 50139-E, 51583-E, 51587-E, 51993-E, 51994-E, 54206-E, 54207-E, 62569-E, 74123-E, 74781-E.)

INFORMATION FILED: February 26, 1942, District of New Jersey, against the Allied Latex Corporation, East Newark, N. J.

ALLEGED SHIPMENT: Between the approximate dates of October 12, 1940, and September 23, 1941, from the State of New Jersey into the States of Georgia, Maryland, Massachusetts, Missouri, New York, Ohio, Pennsylvania, and Rhode Island.

LABEL, IN PART: "Smithies [or "Gems," "Thin-Tex," or "Seal-Test"] Prophylactics," "Liquid Latex," or "Dr. Robinson #333 Disease Preventative * * * Wilson-Robinson Co. Incorporated Boston, Mass."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess. (Samples of the article were found to be defective because of the presence of perforations or holes.)

Misbranding, Section 502 (a), certain statements on the labels and on the article, which represented and suggested that the article was a prophylactic for protection against disease in man and would be efficacious in the prevention of disease in man, were false and misleading.

DISPOSITION: May 14, 1943, a plea of guilty having been entered, the defendant was fined \$5,400.